UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 20 1993

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Classification of Corn Gluten Meal as a Biochemical Pesticide (DP Barcode D193906; Submission No. S445753; ID No. 056872-R; MRID No. 428499-01 to 07)

TO: Leonard Cole/Cynthia Giles-Parker (PM-22)
Herbicide-Fungicide Branch
Registration Division (H7505C)

FROM: John L. Kough, Ph.D., Biologist
Biological Pesticides Section
Science Analysis Branch
Health Effects Division (H7509C)

THROUGH: Roy D. Sjoblad, Ph.D., Section Head
Biological Pesticides Section
Science Analysis Branch
Health Effects Division (H7509C)

ACTION REQUESTED: Gardens Alive! Inc. has requested classification of corn gluten meal (A-Maizing Lawn) as a biochemical pesticide as defined on 40 CFR 158.65. The Registration Division has asked the OPP Biotechnology Workgroup to make this classification determination as established by agreement.

RECOMMENDATION: The OPP Biotechnology Workgroup recommends that corn gluten meal be classified as a biochemical pesticide. This decision is based on the natural occurrence of the pesticidal compound and its non-toxic mode of action as a plant growth regulator.

Based on the information and data supplied, the OPP Biotechnology Workgroup would recommend that corn gluten meal be registered for use in lawns and turf since the data provided and reviewed here is adequate for registration. No additional toxicological or ecological effects information or data are needed.

The Workgroup also suggests OGC consider corn gluten meal uses on turf and lawns (i.e., not on food crops) to be exempted from FIFRA data requirements as a pesticide under 40CFR152.25. This finding could be based on corn gluten meal's meeting the criterion of 40CFR152.25(d), namely, "...consisting of mixtures of plant hormones, plant nutrients, inoculant or soil amendments..." Further, at 40CFR152.25(e) "products consisting of foods and containing no active ingredients, which are used to attract pests"

are also currently exempted from regulation by the Agency. Corn gluten meal would not meet this exemption simply because it does not attract pests.

BACKGROUND: The end-use product, A-Maizing Lawn, is a seedling root growth regulator initially intended for use in lawns and turf. The end-use product is 100% corn gluten meal and is a by-product of normal corn wet milling process for starch and oil extraction.

[redacted]

Information relating the gross chemical composition of a 60% corn gluten meal animal feed was also provided. This sheet indicated that the meal contains 60% protein, all 18 readily distinguishable amino acids, certain vitamins, minerals and was a feed source "rich in xanthophylls which when consumed by broilers impart a bright yellow or golden color to their skin."

The mode of action for corn gluten meal is to prevent the normal development of roots from sprouting seeds; it does not kill directly. When the seedling with less than a normal root system is exposed to drought stress, it succumbs to dehydration. This lack of direct killing action is seen when excessive wetness during weed seed germination reduces product efficacy. Current use rates indicated by the registrant are 20 lbs/1000 sq.ft. for weed reduction in turf.

The corn gluten ingredients responsible for this growth effect are being actively researched at this time. However, the registrant has shown that the active moiety is found only in corn gluten; not in corn starch, corn germ, corn seed fiber or corn meal. The plant growth regulator activity is only found against seedlings; the registrant has shown it has no adverse effect on established plants of Kentucky bluegrass or strawberry. In trials with established bluegrass paddocks, the product was identical to urea or other commercial fertilizers as a slow release source of nitrogen in the absence of any weed control effect.

DISCUSSION: If the registrant identifies the active components and wishes to register this purified product or an analogue, it would require further consideration but may also qualify for biochemical classification.

EPA, OPP, EFED BIOLOGICALS REVIEW

TO: Cynthia Giles-Parker, PM-22 & Leonard Cole
Fungicide-Herbicide Branch
Registration Division (H7505C)

BIOCHEMICAL/MICROBIAL AGENT: Maize/Corn gluten meal

DP BARCODE: D195131

TEST MATERIAL: 100% corn gluten meal

ACTION/STUDY TYPE: 010 New Chemical Screen

STUDY IDENTIFICATION: Data waiver requests for 40 CFR § 158.690 Biochemical nontarget organism data requirements, Guideline reference Nos. 154-6, 154-7, 154-8, 154-9 & 154-10

REVIEWED BY:

Robert I. Rose, Ph.D.
Environmental Fate &
Effects Division (H7507C)

Signature:
Date: 22/MAR/1994

PEER REVIEW BY:

David C. Bays, Ph.D.
Environmental Fate &
Effects Division (H7507C)

Signature:
Date: MAR 24/1994

ADMINISTRATIVE APPROVAL:

Elizabeth M. Leovey, Ph.D
Environmental Fate &
Effects Division (H7507C)

Signature:
Date: 3/25/94

CONCLUSION: A-Maizing Lawn consisting of 100% corn gluten has passed the new chemical screen. This review concludes that registration and use of A-Maizing Lawn consisting of 100.0% corn gluten meal, EPA file symbol 56872-R, would most likely have negligible effects on nontarget organisms. The common food grade nature of the active ingredient and the rationales provided by the applicant are sufficient justification to waive nontarget organism data requirements.

RECOMMENDATIONS: It is suggested that the precautionary statement under Environmental Hazards be upgraded according to PR Notices 93-3 & 93-8 instead of using only "Do not apply directly to water."

BACKGROUND: Waivers of 154-6, 154-7, 154-8 and 154-9 data requirements were supported by the applicant with the following justification: Maize (corn) gluten meal is not expected to cause any adverse effects on nontarget organisms. Corn gluten meal is a food that is used to supplement the diets of animals, birds and fish. Moreover, corn gluten meal provides many of the nutrients, such as protein, fat and fiber which are necessary for these organisms' nutritional and metabolic processes.

The Food and Drug Administration has promulgated a direct food additive regulation stating that corn gluten meal is generally recognized as safe (GRAS). See 21 CFR § 184.1321. Under this regulation, this ingredient can be used in food with no limitation other than current good manufacturing practice. This ingredient may be used as both a nutritional supplement and as a food texturizer.

EPA also recognized that corn gluten meal may be used safely as an inert (or occasionally active) ingredient in pesticide formulations applied to growing crops. EPA has promulgated an exemption from the requirement for a tolerance when corn gluten meal is used as an attractant on crops according to good agricultural practices. See 40 CFR § 180.1001(d).

The applicant appended abstracts from scientific journals which discuss the use of corn gluten meal as bird and fish feed supplement. These articles demonstrate that corn gluten can be used to feed poultry, trout, salmon and catfish.

A waiver of the Guideline 154-10 data requirement was requested because no adverse effects are anticipated on nontarget plants. The product for which registration is sought is intended for preemergence weed control on established lawns and turf. Nontarget plants are not expected to be present on these lawns and turf. Further, the product would not be used in forests, natural grasslands or in forest site preparation. Moreover, the product has a nontoxic mode of action, i.e. it stops root development of annual grassy weeds at the time of germination. The product does not prohibit germination, but it does not allow the weed's root structure to develop sufficiently so that the weed can grow into a healthy plant. As a result, the weed dies from lack of root growth. However, the product does not affect plants with mature root systems. Therefore, no phytoxicity problems are anticipated and no hazard is posed to endangered and threatened plant species.

The applicant has submitted efficacy studies with the application package which show that the active ingredient is selective in controlling target species. In these studies, target weeds were controlled, but strawberry plants and Kentucky bluegrass were not adversely affected.

DISCUSSION OF INDIVIDUAL SUBMITTED STUDIES: Individual studies were not submitted for review.

COMPLETION OF ONE-LINER: None

CBI APPENDIX: None

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BRIEFING MEMORANDUM

SUBJECT: Registration of the New Chemical Corn Gluten Meal

FROM: Stephen Johnson, Acting Director
Registration Division (7505C)

TO: Daniel M. Barolo, Acting Director
Office of Pesticide Programs (7501C)

Background:

On July 2, 1993, Gardens Alive, Inc. submitted an application for registration for corn gluten meal as a preemergent weed control for lawns. At the time of submission of the application for registration, Gardens Alive, Inc. also submitted a request for biochemical classification. On August 20, 1993 the OPP Biotech Workgroup classified corn gluten meal as a biochemical.

The mode of action of corn gluten meal is to prevent the normal development of roots from sprouting seeds. It does not kill directly. More specifically, corn gluten meal causes seedlings with less than normal root systems to succumb to dehydration when exposed to drought stress. The plant growth regulator activity is only found against seedlings. Gardens Alive has shown, through trials, that corn gluten meal has no adverse effect on established plants such as Kentucky bluegrass and strawberry.

Corn gluten meal will be marketed under the trade name A-Maizing Lawn. It is a selective herbicide used to control the following annual grasses: crabgrass, creeping bentgrass, smart weed, dandelions, redroot bigweed, purslane, lambsquarter, foxtail, barnyard grass, and Bermuda grass.

SCIENCE FINDINGS

Product Chemistry

All data requirements have been fulfilled. The registrant did not submit an application for a manufacturing use product because the technical grade active ingredient is the same as the end-use formulation.

Toxicology

All toxicology data required to support the registration for this biochemical have been waived. No additional toxicological data are needed. The decision to waive the toxicology data are based on the fact that the product is naturally occurring, possesses a non-toxic mode of action, and meets the criterion of vitamin hormone products under 40 CFR § 152.25(d).

Ecological Effects

A review of the data waiver requests conclude that corn gluten meal would most likely have negligible effects on non-target organisms. The common food grade nature of the active ingredient and the fact that corn gluten meal is not expected to cause any adverse effects on non-target organisms provide rationales for waiving the data. Additionally, corn gluten meal is a food that is used to supplement the diets of animals, birds and fish. Moreover, corn gluten meal provides many of the nutrients, such as protein, fat and fiber, which are necessary for these organisms' nutritional and metabolic processes.

The Food and Drug Administration has promulgated a direct food additive regulation stating that corn gluten meal is generally recognized as safe (GRAS). EPA also recognizes that corn gluten meal may be used safely as an inert (or occasionally active) ingredient in pesticide formulations applied to growing crops.

Corn gluten meal is intended for preemergent weed control on established lawns and turf. Nontarget plants are not expected to be present on these lawns and turf. Further, this product would not be used in forests, natural grasslands or in forest site preparation. No phytotoxicity problems are anticipated and no hazard is posed to endangered and threatened plant species; therefore, no additional ecological effects information or data are needed.

Environmental Fate and Groundwater

No environmental fate and groundwater data are required since all ecological effects data are waived. Environmental Fate and Groundwater data (Tier II) are conditionally required if the results of data submitted under Ecological Effects (Tier I) trigger such testing. The data for Ecological Effects (Tier I) are waived; therefore, Environmental Fate and Groundwater data (Tier II) testing was not triggered and is not required.

Recommendations

The registration of corn gluten meal will present less of a toxicological risk to humans and non-target organisms as opposed to other preemergent herbicides currently used on lawns and turf. Corn gluten meal is expected to replace or be used in substitute of oxadiazon, benefin, atrazine, bensulfide, dacthal, dimethylamine 2,4 dichlorophenxyacetate, prodiamine, oryzalin, and trifluralin. All of these herbicides present either acute toxicities or toxicological effects that are not expected from corn gluten meal.

Therefore, based on the adequacy of data that have been submitted to the Agency for registration, I recommend that you concur with the Section 3(c)(5) registration of the new chemical active ingredient, corn gluten meal, for use on lawns and turf.

CONCUR: _____

DO NOT CONCUR: _____

DATE: 5/25/94